

ASPIERA ANTI-FUNGAL - clotrimazole ointment

Aidance Skincare & Topical Solutions, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Clotrimazole 1%

Purpose

Antifungal

Uses

- Cures finger and toe area fungal infections.
- For effective relief of itching, scaling, cracking, burning, discoloration, soreness, irritation, discomfort and chafing associated with fungal infection.

Warnings

For external use only. Do not use on children under 2 years of age unless directed by a doctor. When using this product avoid contact with eyes.

Keep out of reach of children.

If swallowed, call poison control or seek medical help.

Stop and use and ask a doctor if irritation occurs or there is no improvement within 4 weeks.

Directions

- For nail care, wash and dry affected skin. Apply a thin layer of Aspiera around and under entire nail and cuticle twice daily (morning and night) or as directed by a doctor.
- If you see improvement within 4 weeks of use, you may continue use until satisfactory results are obtained.
- For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks.
- If condition persists longer, consult a doctor. Intended for use by normally healthy adults only. Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor. Supervise children in the use of this product.

Other Information

Store at room temperature.

Inactive Ingredients

bentonite clay, cera alba (organic beeswax), magnesium oxide, peppermint oil, silver oxide, simmondsia chinensis (jojoba) seed oil, tea tree oil, zinc oxide

Made in USA. Distributed by Aspiera Medical, Woonsocket, RI 02895. (+1) 401-400-0047
www.aspiera.com

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PRINCIPAL DISPLAY PANEL - 44g Jar

Aspiera

Anti-Fungal Ointment

Faster Penetration for Faster Healing™

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Faster Penetration for Faster Healing™

Aspiera™

Anti-Fungal Ointment

NET WT 44 grams

Directions (continued): If you see improvement within 4 weeks of use, you may continue use until satisfactory results are obtained. For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ingrown, use daily for 4 weeks. If condition persists longer, consult a doctor. Intended for use by normally healthy adults only. Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor. Supervise children in the use of this product.

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Aspiera Medical

0 857-397-00229

N 24909-606-44

AD

ASPIERA ANTI-FUNGAL

clotrimazole ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-606
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)		CLOTRIMAZOLE	1.0 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-606-44	44 g in 1 JAR		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part333C		05/31/2012	

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-606) , label(24909-606)	